CV 07 1310

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Robert A. Smith and Scott J. Sebastian, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

ELI LILLY AND COMPANY, SIDNEY TAUREL, CHARLES GOLDEN, and ALAN BREIER, M.D.

Defendants.

Case No.: _____

CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

Jury Trial Demanded

WEINSTEIN, J.

Richard A. Smith and Scott J. Sebastian ("Plaintiffs"), individually and on behalf of all other persons and entities who purchased or otherwise acquired securities issued by Eli Lilly and Company ("Lilly" or the "Company") between March 28, 2002 and December 22, 2006, by their undersigned attorneys, for their Class Action Complaint ("Complaint"), allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters.

Plaintiffs' information and belief is based on their investigation (made by and through their attorneys), which investigation included, among other things, a review and analysis of: (1) public documents pertaining to the defendants; (2) Lilly's filings with the Securities and Exchange Commission ("SEC"); (3) press releases published by Lilly; (4) analyst reports concerning the Company; (5) pleadings in litigation naming Lilly as a defendant; and (6) newspaper and magazine articles (and other media coverage) regarding Lilly and its business.

Many of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their custody and/or control. Plaintiffs believe that further substantial evidentiary support will exist for the allegations in this Complaint after a reasonable opportunity for discovery.

## I. SUMMARY OF THE ACTION

1. This is a securities class action brought on behalf of all purchasers of Lilly's publicly traded securities between March 28, 2002 and December 22, 2006, inclusive (the "Class Period"), which securities were artificially inflated as a result of violations of the federal securities laws arising out of defendants' dissemination of false and misleading statements concerning Zyprexa, the Company's best-selling product.

2. Sales of Zyprexa grew from $3.69 billion to $4.42 billion between 2002 and 2004, and Lilly's stock price increased from $43.75 per share to $76.95 per share between July 18, 2002 and May 7, 2004. Throughout the class period, Lilly had internal information concerning a dangerous connection between the use of Zyprexa and extreme weight gain and diabetes. During the Class Period, in the face of mounting independent research connecting Zyprexa to diabetes and weight gain, and lawsuits by persons who suffered these side-effects, Lilly emphatically denied any such link. Yet, as public agencies raised warnings about the safety of Zyprexa, sales slowed -- and Lilly's stock price dropped from $76.95 per share to $50.34 per share between May 7, 2004 and October 25, 2004 (representing a loss of market capitalization of over $30 billion).

3. However, recent reports in *The New York Times* demonstrate that Lilly knew of the very health risks that it denied repeatedly and that the Company also purposefully marketed Zyprexa for illegal, off-label uses. Thus, the over $30 billion dollar decline in Lilly's market

capitalization between May 7, 2004 and October 25, 2004 was the direct result of defendants' fraudulent conduct.

4. Articles appearing in *The New York Times* between December 17 and 21, 2006 publicly disclosed for the first time that (a) the Company had engaged in a decade-long effort to play down the health risks of Zyprexa; and (b) Lilly actively marketed Zyprexa for illegal off-label uses (such as to treat older patients with symptoms of dementia). The publication of those articles caused an additional $3.49 per share decline in the Company's stock price (or 6.4 percent), and represented a further market loss of approximately $3.5 billion.

5. Plaintiffs have brought this class action on behalf of similarly situated Lilly shareholders to seek redress for the damages caused by the defendants' unscrupulous and manipulative conduct.

## II. JURISDICTION AND VENUE

6. This action arises under Sections 10(b), and 20(a) of the Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

7. This Court has subject-matter jurisdiction over this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331.

8. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391. Many of the acts and practices complained of herein, including the misrepresentations and schemes alleged herein, occurred in substantial part in this District.

9. This District is also the venue for numerous product liability actions relating to the sales of Zyprexa by Eli Lilly, consolidated within this District as *In re Zyprexa Products Liability Litigation,* Civ. No. 04-MD-1596-JBW, which were transferred to this District by the Judicial Panel on Multidistrict Litigation, by order dated May 15, 2004.

10. In connection with the acts, transactions and conduct alleged herein, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States' mails, interstate telephone communications and the facilities of a national securities exchange and market.

## III. PARTIES

11. Plaintiff Robert A. Smith is a citizen of the State of California. Plaintiff Scott J. Sebastian is a citizen of the State of Illinois. As set forth in their accompanying certifications (incorporated by reference herein), Plaintiffs purchased the publicly traded securities of Lilly at artificially inflated prices during the Class Period.

12. Defendant Lilly is an Indiana corporation with its principal executive offices located at Lilly Corporate Center, Indianapolis, Indiana 46285. Through its subsidiaries, Lilly engages in the discovery, development, manufacture, and sale of pharmaceutical products in the United States and internationally. The Company offers neuroscience products, including Zyprexa for schizophrenia, bipolar mania, and bipolar maintenance; Cymbalta for depression and diabetic peripheral neuropathic pain; Strattera for attention-deficit hyperactivity disorder in children, adolescents, and adults; Prozac for depression, and for bulimia and obsessive-compulsive disorders; Permax for Parkinson's disease; Sarafem for pre-menstrual dysphoric disorders; Symbyax for bipolar depression; and Yentreve for stress urinary incontinence. Lilly's common stock is traded on New York Stock Exchange ("NYSE") under the symbol "LLY."

13. Defendant Sidney Taurel ("Taurel") is the Company's Chairman and Chief Executive Officer. Defendant Taurel became Lilly's Chief Executive Officer in July 1998 and Chairman of the Company's Board of Directors on January 1, 1999. He also served as Lilly's President from February 1996 through September 2005 and has been a member of Lilly's Board of Directors since 1991. Defendant Taurel participated in the issuance of, signed, and/or

certified as accurate, the Company's false and misleading SEC filings identified in Section VII herein. Because of Defendant Taurel's position, he knew the adverse non-public information about the business of Lilly as well as its finances and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management (and/or Board of Directors') meetings and via reports and other information provided to him in connection therewith.

14. Defendant Charles Golden ("Golden") was, from 1996 until April 30, 2006, the Company's Executive Vice President and Chief Financial Officer. He also served as one of the Company's directors from 1996 until April 2006. On February 23, 2006, the Company announced that Defendant Golden would retire from his positions with Lilly effective April 30, 2006. Defendant Golden participated in the issuance of, signed, and/or certified as accurate, the Company's false and misleading SEC filings identified in Section VII herein. Because of Defendant Golden's position, he knew the adverse non-public information about the business of Lilly as well as its finances and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management (and/or Board of Directors') meetings and via reports and other information provided to him in connection therewith.

15. By certifying (where required by the Sarbanes-Oxley Act of 2002), the Company's SEC filings identified herein, Defendants Taurel and Golden represented that: (a) such reports did not contain any untrue statement of a material fact (or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading); and (b) the financial statements, and other financial

information included in such reports, fairly presented in all material respects the Company's financial condition and results of operations.

16. Defendant Alan Breier, M.D. ("Breier") was named Lilly's Vice President for Medical and Chief Medical Officer in August 2003. Defendant Breier also is a member of the Lilly Research Laboratories policy committee and the Company's senior management council. Previously, Breier was a Lilly clinical research fellow, Zyprexa product team leader, and Vice President of Pharmaceutical Products for Lilly. As detailed herein, during the Class Period, Defendant Breier, *inter alia*, made numerous false and misleading statements. Because of Defendant Breier's position, he knew the adverse non-public information about the business of Lilly as well as its finances and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management meetings and via reports and other information provided to him in connection therewith.

17. Collectively, defendants Taurel, Golden and Breier are referred to herein as the "Individual Defendants." The Individual Defendants and Lilly are collectively referred to herein as the "Defendants."

## IV. CONTROL PERSON ALLEGATIONS/GROUP PLEADING

18. By virtue of the Individual Defendants' positions within the Company, they had access to undisclosed adverse information about its business, operations, operational trends, finances, and present and future business prospects. The Individual Defendants would ascertain such information through Lilly's internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, conversations and connections with vendors and customers, attendance at sales, management, and Board of

Directors' meetings, including committees thereof, and through reports and other information provided to them in connection with their roles and duties as Lilly officers and directors.

19. It is appropriate to treat the Individual Defendants collectively as a group for pleading purposes and to presume that the materially false, misleading and incomplete information conveyed in the Company's public filings and press releases as alleged herein was the result of the collective actions of the Individual Defendants identified above. The Individual Defendants, by virtue of their high-level positions within the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information concerning the Company and its business, operations, prospects, growth, finances, and financial condition, as alleged herein.

20. The Individual Defendants were involved in drafting, producing, reviewing, approving and/or disseminating the materially false and misleading statements and information alleged herein, were aware of or recklessly disregarded the fact that materially false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

21. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that

the market price of the Company's publicly traded securities would be based upon truthful and accurate information. The Individual Defendants' material misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

22. The Individual Defendants, by virtue of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, they are responsible for the accuracy of the public reports and releases detailed herein.

## V. CLASS ACTION ALLEGATIONS

23. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class (the "Class") of all persons who purchased or otherwise acquired Lilly securities during the Class Period, and who were damaged thereby. The Class Period is from March 28, 2002 through December 22, 2006.

24. Excluded from the Class are the Defendants herein, members of the immediate families of the Individual Defendants, any parent, subsidiary, affiliate, officer, or director of Defendant Lilly, any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors and assigns of any excluded person.

25. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of members of the Class is unknown to Plaintiffs at the present time and can only be ascertained from books and records maintained by Lilly and/or its agent(s), Plaintiffs believe that there are tens of thousands of members of the Class located throughout the United States. As of February 15, 2006, Lilly had issued and outstanding

1,129,982,580 shares of common stock. Throughout the Class Period, Lilly common stock was actively traded on the NYSE, with more than 4.591 billion shares traded during the Class Period.

26. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class. Plaintiffs have retained extremely competent counsel experienced in class and securities litigation and intend to prosecute this action vigorously. Plaintiffs are members of the Class and do not have interests antagonistic to, or in conflict with, the other members of the Class.

27. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class purchased Lilly securities at artificially inflated prices and have sustained damages arising out of the same wrongful course of conduct.

28. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by the Defendants' acts and omissions as alleged herein;

(b) Whether the Defendants participated in and pursued the common course of conduct and fraudulent scheme complained of herein;

(c) Whether the Defendants had knowledge of (or were reckless with respect to) the improper activities described herein;

(d) Whether the statements disseminated to the investing public, including investors in Lilly, during the Class Period omitted and/or misrepresented material facts about Lilly's true financial condition, business operations and future business prospects;

(e) Whether Defendants acted knowingly or recklessly in omitting to state and/or misrepresenting material facts;

(f) Whether the market price of Lilly's securities during the Class Period was artificially inflated due to the non-disclosures and/or misrepresentations complained of herein; and

(g) Whether Plaintiffs and the other members of the Class have sustained damages and, if so, the appropriate measure thereof.

29. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since, among other things, joinder of all members of the Class is impracticable. Furthermore, as the damages suffered by many individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for Class members individually to seek redress for the wrongful conduct alleged. Plaintiffs do not foresee any difficulty in the management of this litigation that would preclude its maintenance as a class action.

30. The names and addresses of the record owners of the shares of Lilly common stock and other securities purchased during the Class Period are available from Lilly and/or its transfer agent(s). Notice can be provided to persons who purchased or otherwise acquired Lilly common stock by a combination of published notice and first class mail, using techniques and forms of notice similar to those customarily used in other class actions arising under the federal securities laws.

## VI. OVERVIEW OF LILLY'S FRAUDULENT SCHEME

31. Each of the Defendants is liable as a participant in a scheme, plan and course of conduct that operated as a fraud and deceit on Class Period purchasers of the Company's

securities. Throughout the Class Period, Defendants disseminated materially false and misleading statements and suppressed material adverse facts about Zyprexa. Among other fraudulent conduct, the Defendants concealed (a) serious health risks associated with the drug (including a known link with diabetes) and (b) that Lilly had illegally marketed Zyprexa for unapproved uses.

32. Throughout the Class Period, Lilly told investors in numerous filings with the SEC that it had allegedly "implemented and continue[d] to review and enhance a broadly based compliance program that include[d] comprehensive compliance-related activities ***designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best-price reporting comply with applicable laws and regulations.***" (emphasis added).

33. During the Class Period, the Company also boasted publicly regarding its purported adherence to strict ethical standards. By way of example, in its Form 10-K dated March 1, 2006, Lilly stated that it had "adopted a code of ethics that complies with the applicable SEC and New York Stock Exchange requirements" and further that this ethical code was set forth in, among other places, "The Red Book," which is a "comprehensive code of ethical and legal business conduct applicable to all employees worldwide and to our Board of Directors." Lily further noted that "The Red Book" was available on line at its corporate web site.

34. As set forth on the Company's web site, "The Red Book" states, *inter alia*, that:

> **Integrity** - We must conduct our business consistent with all laws, regulations, and government and court orders and decrees applicable to Lilly business, and be honest in our dealings with employees, customers, suppliers, competitors, shareholders, and communities. We must always strive to do the right thing.

(emphasis in original). "The Red Book" also provides that:

> ***Honesty and integrity are vital to the success of our business. To operate with integrity, we must be honest in our dealings with coworkers, government and political officials, customers, suppliers, competitors, shareholders, and the community.*** We must avoid even the appearance of conflicts of interest. We must not bribe or attempt to unduly influence government and political officials, customers, and suppliers. We must compete fairly and openly while complying with all legal requirements applicable to Lilly business regarding competition. ***Whenever we conduct business, we must do so consistent with all laws, regulations, and government and court orders and decrees applicable to Lilly business.*** . . .
>
> ***We will do business only by lawful, ethical means. We will negotiate, perform our obligations, and market our products in good faith to preserve our reputation for fair and honest dealings.***

(emphasis added).

35. "The Red Book" also contains a section entitled "Ethical Interactions With Health Care Providers and Promotion of Pharmaceutical Products," which states, in relevant part, that employees involved in sales and marketing activities ***must***, *inter alia*: (a) "[p]romote Lilly products only for their locally approved indications" and (b)"[n]ot proactively discuss information about unapproved new products or off-label information."

36. However, notwithstanding that it purportedly "implemented . . . a broadly based compliance program" (and that it allegedly adhered to strict ethical standards), throughout the Class Period, the Defendants deceived the public at large in two (2) material respects. First, the Defendants concealed information about the side effects of Zyprexa. Second, in order to increase profits, the Defendants engaged in a massive illegal off-label marking campaign to get primary care physicians to prescribe Zyprexa for uses never approved by the U.S. Food and Drug Administration ("FDA").

37. By way of background, Zyprexa is Lilly's best-selling product with sales of $4.2 billion in 2005. Since Lilly introduced Zyprexa in 1996, about 20 million patients worldwide have received the drug, which helps control the hallucinations and delusions associated with

schizophrenia and severe mania. Zyprexa was approved by the FDA for the treatment of schizophrenia in 1996 and for the treatment of bipolar mania in 2000.

38. From Zyprexa's introduction to the market in 1996, through 2005, the drug's sales increased rapidly:

| Year | Total Sales of Zyprexa (in millions of dollars) |
|---|---|
| 2005 | 4,202 |
| 2004 | 4,419 |
| 2003 | 4,277 |
| 2002 | 3,689 |
| 2001 | 3,087 |
| 2000 | 2,360 |
| 1999 | 1,885 |
| 1998 | 1,443 |
| 1997 | 730.2 |

**A. Lilly Conceals The Known Link Between Zyprexa and Diabetes.**

39. For almost a decade, the Defendants knew of the health hazards associated with Zyprexa use. Yet, the Defendants affirmatively and actively concealed information from the public at large (including investors in the Company's securities) which clearly demonstrated the dangers of Zyprexa. Indeed, the Defendants affirmatively misled the public with regard to the material and clear risks of Zyprexa.

40. By way of example, in March 2003, a Lilly spokesperson told the *Baltimore Sun* that "[n]o one has yet proved any sort of causality [between Zyprexa and diabetes]." *See*

Timothy Wheeler, *Risks From Mental Illness Drug Not Adaquately Noted, Some Say Studies Link Zyprexa To Diabetes Deaths*, BALTIMORE SUN, Mar. 19, 2003. In April 2003, Defendant Breier stated publicly that "[t]here is no evidence anybody has produced to date that says antipsychotic drugs cause diabetes." Jeff Swiatek, *Lilly Confronts Medical Lawsuits Stemming from Popular Schizophrenia Drug*, INDIANAPOLIS STAR, Apr. 13, 2003. Later that same month, Defendant Breier stated that "[s]cientific data has not established that Zyprexa -- or any antipsychotic medications -- causes diabetes." Alan Breier, *Letters to the Editor: Evidence Backs Efficiency And Safety Of Zyprexa*, WALL ST. JOURNAL, Apr. 28, 2003.

41. Lilly had a clear economic interest in concealing such known health risks. Since its introduction, Zyprexa has become the Company's all time best selling drug, generating over worldwide sales of $4.4 billion in 2004 alone (and accounting for 32% of the Company's revenue during that calendar year).

42. However, Lilly's own pre-clinical studies regarding Zyprexa demonstrated that the drug caused weight gain and hypoglycemia (low blood sugar). In addition, following the drug's release, Lilly became aware of a large number of adverse event reports ("AERs") on file with the FDA's Medwatch database involving diabetes-related illnesses associated with the use of Zyprexa.

### B. *The New York Times* Reveals Lilly's Multi-Year Scheme to Conceal the Zyprexa-Diabetes Link.

43. The truth about the Defendants' long-standing scheme to affirmatively mislead the public regarding the health risks of Zyprexa finally was revealed by THE NEW YORK TIMES in December 2006. In a report appearing on December 17, 2006, the paper stated that Lilly "has engaged in a decade-long effort to play down the health risks of Zyprexa . . . according to hundreds of internal Lilly documents and e-mail messages among top company managers." *See*

Alex Berenson, *Lilly Said To Play Down Risk Of Top Pill*, N.Y. TIMES, Dec. 17, 2006, at 11. Specifically, THE NEW YORK TIMES article states that Lilly had knowledge of clinical trials and other information demonstrating strong evidence of a causal link between Zyprexa use and diabetes. This report makes clear that the Defendants failed to adequately warn patients and doctors about the dangers of the drug (and also withheld material facts from the investing public at large throughout the Class Period).

44. The press report in question detailed secret internal Company documents (which had never before been disclosed publicly) establishing that Lilly knew, for an extended period, that Zyprexa caused diabetes. More specifically, the article noted that:

- In a November 1999 email, Defendant Breier stated in an email to two dozen Lilly employees: "[Zyprexa]-associated weight gain and possible hyperglycemia [high blood sugar] is a major threat to the long-term success of this critically important molecule."
- In 2000, a group of doctors retained by Lilly to consider the link between Zyprexa and diabetes gave the following warning to the Company: "[U]nless we come clean on this, it could get much more serious than we might anticipate."
- In both 2000 and 2001, Lilly's research showed that psychiatrists consistently said that many more of their patients developed diabetes when on Zyprexa than when on other anti-psychotic drugs. For example, the Company found that 70 percent of psychiatrists polled had seen at least one of their patients develop high blood sugar or diabetes while taking Zyprexa.
- Lilly instructed sales representatives to play down studies that the Company conducted showing that 30 percent or more of patients gained 22 pounds after a year on Zyprexa.

Not surprisingly, the Company has denied wrongdoing in this regard. ***Indeed, in a response to The NEW YORK TIMES article, the Company stated that "[i]n summary, there is no scientific evidence establishing that Zyprexa causes diabetes."***

45. On December 21, 2006, THE NEW YORK TIMES ran a follow up story – this time revealing that additional confidential (and never before released) internal Company documents

established that between February 2000 and late 2001, Lilly withheld information from the public about the risks of Zyprexa use. More specifically, this article stated:

- Lilly waited over a year to disclose a February 2000 clinical trial findings that patients on Zyprexa were 3.5 times more likely to experience high blood sugar than persons taking a placebo.

- In November 1999, Lilly did not disclose a Company review of 70 clinical trials that showed that 16 percent of patients taking Zyprexa for a year gained more than 66 pounds. Rather, it disclosed the results of a review of a smaller sample of clinical trials showing that about 30% of patients gained 22 pounds.

Alex Berenson, *Disparity Emerges in Lilly Data on Schizophrenia Drug*, N.Y. TIMES, Dec. 21, 2006, at C1.

46. As noted below, however, the Company's deceitful conduct was not limited to concealing the health dangers associated with Zyprexa use. ***In December 2006, The NEW YORK TIMES also revealed that still other internal Company documents established that Lilly had marketed Zyprexa for off-label use.***

**C. The Company Knowingly Engages in the Off-Label Marketing of Zyprexa.**

**(1) The Food And Drug Administration's Prohibition Of Off-Label Marketing**

47. A manufacturer may distribute a drug only if it is approved by the FDA. *See* 21 U.S.C. § 355(a). In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" for all "conditions prescribed, recommended, or suggested" on a drug's label. 21 U.S.C. § 355(d).

48. A drug is considered misbranded if its label does not contain, *inter alia*, "[s]tatements of all conditions, purposes, or uses for which such drug is intended." 21 C.F.R. § 201.5. *See also* 21 U.S.C. § 331(a) (prohibiting the introduction of misbranded drugs into interstate commerce); 21 U.S.C. § 352(f) (stating that a drug is misbranded if it does not contain "adequate directions for use"). The term "intended" in 21 C.F.R. § 201.5 refers to "the objective

intent of the persons legally responsible for labeling drugs [*e.g.*, the manufacturer]." 21 C.F.R. § 201.128. Therefore, if a manufacturer intends that a drug be used for a certain purpose, information about that purpose must be on the drug's label and approved as safe by the FDA.

49. Where a manufacturer directly advertises a drug for a particular use, that use is considered an intended use. *See* 21 C.F.R. § 201.128 ("[I]ntent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by . . . [manufacturers] or their representatives."). Therefore, if a drug's manufacturer advertises uses not on its FDA-approved label, the drug is considered misbranded and its distribution in interstate commerce is prohibited. *See* 21 U.S.C. §§ 331(a) and (d).

50. Furthermore, depending on the circumstances, if a manufacturer promotes off-label use indirectly – for example, by sponsoring continuing medical education ("CME") courses that promote off-label use – such off-label use may be considered an intended use if the manufacturer intended that the drug be used for off-label purposes. *See* 21 C.F.R. § 201.128 ("It may be shown by the circumstances that the article is, with the knowledge of . . . [the manufacturer] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.").

51. However, the FDA has created certain avenues for manufacturers to communicate off-label information to doctors. A manufacturer may forward off-label information in medical and scientific publications to a physician in response to an unsolicited request. *See* 21 U.S.C. § 360aaa-6. Also, manufacturers may disseminate off-label information to a physician, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State governmental agency ***if*** the manufacturer, *inter alia*, discloses that the use is off-label ***and*** provides the disseminated material to the FDA. *See* 21 U.S.C. §§ 360aaa(a)-(c); 360aaa-1.

52. Notwithstanding the FDA's regulation of manufacturers, the FDA does not regulate how doctors prescribe drugs. Physicians may prescribe approved drugs for any purpose that he or she sees fit. ***That being said, however, while off-label prescribing by physicians is legal, the FDA prohibits drug companies from promoting such off-label use to doctors.*** *See* 21 U.S.C. § 331(d) (prohibiting distribution of drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a "misbranded" drug). *See also U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) ("Though physicians may prescribe drugs for off-label usage, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved.").

53. Lilly was well aware of the legal restrictions prohibiting off-label marketing, and the legal implications of a drug's FDA-approved label. However, as discussed below, Lilly's marketing of Zyprexa was specifically designed to promote Zyprexa for non-medically accepted indications. By so promoting the use of Zyprexa, Lilly knowingly marketed the drug for off-label use, in violation of federal law.

**(2) Lilly Illegally Markets Zyprexa for Uses Not Indicated on the Drug's FDA-Approved Label.**

54. In 1996, the FDA approved Zyprexa for the short-term treatment of schizophrenia. In 2000, the FDA approved the drug for the long-term treatment of schizophrenia, and also for the short-term treatment of acute manic episodes associated with bipolar I disorder. Notwithstanding that the FDA only had approved Zyprexa for the foregoing uses, throughout the Class Period, Lilly aggressively off-label marketed Zyprexa to practicing physicians when it knew that such off-label marketing was not approved by the FDA. More specifically, Lilly actively encouraged primary care physicians to use Zyprexa in patients who did not suffer from either schizophrenia or bipolar I disorder.

55. The off-label use of Zyprexa can lead to dangerous side effects. For example, in 2005, the FDA ordered manufacturers of several atypical anti pyschotic drugs, including Zyprexa, to add a so-called "black box label" that warns of a higher death rate among elderly dementia patients taking the drugs, and that the drugs are not approved to treat symptoms of dementia in the elderly (a "black box label" is the strongest warning that a drug can carry).

56. Beginning in 2004, accusations began to surface that Lilly had engaged in the off-label marketing of Zyprexa, its bestselling product, to patients for whom it was inappropriate and possibly dangerous. In March 2004, the U.S. Attorney for the Eastern District of Pennsylvania commenced an investigation into Lilly's marketing practices concerning Zyprexa. In June 2005, Lilly received a subpoena from the office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking the production of documents relating to sales of Zyprexa and Lilly's marketing and promotional practices with respect to Zyprexa. In February 2006, the states of West Virginia and Alaska filed lawsuits against Lilly alleging, among other things, that the Company marketed Zyprexa for unapproved uses. In July 2006, the State of Mississippi filed suit against Lilly alleging that Company representatives persuaded doctors in the state to prescribe Zyprexa to patients suffering from conditions such as anxiety, mood swings and disturbed sleep -- when the drug was approved only to treat bipolar disorder and schizophrenia.

57. Notwithstanding these various developments, the Company steadfastly denied that it marketed Zyprexa for off-label use. Indeed, just days before THE NEW YORK TIMES first disclosed publicly Lilly's illicit and unlawful off-label marketing scheme, a Company spokesman stated: "[w]e firmly believe that these allegations are without merit . . . ***We are committed to follow the highest ethical standards and to promote our medications only for***

***approved uses.***" *Payers Seek Zyprexa Refund; Possible Class Action Suits Accuse Lilly of Illegally Marketing Drug*, INDIANAPOLIS BUSINESS JOURNAL, Dec. 11, 2006 (emphasis added).

58. While not known to investors until December 18, 2006 (when detailed evidence of their malfeasance first was disclosed publicly in an article appearing in THE NEW YORK TIMES), throughout the Class Period (and, indeed, dating back to 1999), the Defendants engaged in an illicit scheme to offset a drop in sales that was sure to result (and, in point of fact, did result) from reports of Zyprexa's side effects (diabetes), by promoting the writing of Zyprexa prescriptions to a wider spectrum of patients. In this regard, secret internal Company documents indicate that Lilly's sales representatives were encouraged to conceal Zyprexa's side effects and to suggest that the drug, which was approved for use only for schizophrenic and bipolar patients, ought to be prescribed for elderly patients with dementia as well -- despite the fact that the FDA had expressly warned (in April 2005) that Zyprexa increases the risk of death among older patients suffering from that condition.

59. In addition, unbeknownst to the investing public, Lilly also encouraged the prescribing of Zyprexa to patients suffering from depression, another condition for which the drug was not originally intended. As noted above, federal law prohibits drug manufacturers from encouraging doctors to prescribe drugs to patients for whom their use has not been approved by the FDA. *See, supra*, at ¶ 52.

60. The Company's illicit off-label marketing campaign was enormously effective -- Zyprexa sales doubled to $3 billion between 1999 and 2002, and during 2005 alone, Lilly sold $4.2 billion worth of Zyprexa to over 2 million people worldwide.

61. On December 18, 2006, THE NEW YORK TIMES reported that secret internal Company documents established that Lilly marketed off-label uses of Zyprexa since 1999 to

treat (1) dementia in the elderly and (2) persons who exhibited potential mild bipolar or schizophrenia symptoms, but who were not diagnosed with either disease. *See* Alex Berenson, *Drug Files Show Maker Promoted Unapproved Uses*, N.Y. TIMES, Dec. 18, 2006, at A1. Prior to the release of the December 18, 2006 article, the public at large had no knowledge of the lengths to which Lilly had gone to promote the off-label use of Zyprexa.

62. Specifically, THE NEW YORK TIMES article in question referenced:

- A memo written in 1999 or 2000 by a marketing executive brainstorming regarding how to get primary care physicians rather than just psychiatrists to prescribe Zyprexa stated that "dementia [an off-label use] should be first message" because primary care physicians treat dementia and not bipolar disorder. The document further stated that primary care physicians "might prescribe outside of label."

- Marketing material for doctors produced in 2001 in which Lilly recommended Zyprexa for patients for whom the drug was not approved. For example, the article highlighted one brochure recommending Zyprexa for a woman who merely had disturbed sleep.

- A 2002 marketing brochure for doctors that recommended Zyprexa for a person who never was diagnosed with bipolar disorder, but who felt irritable and who was reported to be talkative, elated, and needing little sleep.

- An August 2001 email message from a doctor to Lilly and the FDA complaining about a Lilly presentation where the drug was recommended for use by an elderly female with insomnia, agitation, slight confusion, and no physical finding to explain these symptoms. Again, this woman was not diagnosed with bipolar disorder or schizophrenia.

63. The article further added that:

> ***The documents also show that Lilly encouraged primary care doctors to treat the symptoms and behaviors of schizophrenia and bipolar disorder even if the doctors had not actually diagnosed those diseases in their patients***. Lilly's market research had found that many primary care doctors did not consider themselves qualified to treat people with schizophrenia or severe bipolar disorder.
>
> ***The campaign was successful***, the [Lilly] documents show. By March 2001, about three months after the start of Viva Zyprexa, the campaign had led to 49,000 new prescriptions, according to a presentation that Michael Bandick, the brand manager for Zyprexa, gave at a national meeting of Lilly sales representatives in Dallas.

(emphasis added).

64. Not surprisingly, Lilly has denied the substance of the December 18, 2006 article detailing the Company's off-label marketing of Zyprexa. In this regard, Dr Steven Paul, Lilly's executive vice president, science and technology stated:

> [a]t Lilly, we do not engage in off-label promotion - as alleged in *The Times* article. Lilly is committed to the highest ethical standards and to promoting our medications only for approved uses. We have clear guidelines and extensive training for our sales representatives to help assure that they provide appropriate promotional information that is within the scope of prescribing information approved by the FDA.

**(3) THE NEW YORK TIMES Articles Cause Lilly's Stock Price To Drop.**

65. On Friday December 15, 2006, Lilly's stock closed at $54.52 per share. After publication of THE NEW YORK TIMES articles regarding Zyprexa on Sunday December 17 and Monday December 18, 2006, the stock price dropped to $54.05 per share on Monday December 18. The stock price continued to decline and by December 22, 2006, reached a low of $51.13 per share. Therefore, in the immediate aftermath of these various news reports, Lilly's stock price declined by $3.49 per share or 6.4 percent.

## VII. FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

66. As detailed herein, during the Class Period, the Defendants issued or caused to be issued materially false and misleading statements that deceived the investing public as to the Company's financial performance, condition and prospects.

67. Many of the Company's false and misleading statements during the Class Period were made in Form 10-K's that were certified by Defendant Taurel and Defendant Golden in accordance with the Sarbanes-Oxley Act of 2002. By certifying those public filings, Defendants Taurel and Golden represented, *inter alia*, that they did not contain any untrue statement of a

material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by such filings.

**A. Form 10-K for Fiscal Year 2001**

68. The Class Period begins on March 28, 2002. On that date, Lilly filed with the SEC a Form 10-K for Fiscal Year 2001 (ending December 31, 2001). Defendants Taurel and Golden signed Lilly's Form 10-K for Fiscal Year 2001. In that public filing, the Company reported that its worldwide sales for 2001 had increased by 6 percent, to $11.54 billion. According to the Company, this sales growth "was led," *inter alia*, "by Zyprexa, a treatment for schizophrenia and related psychoses." The Company added that:

> Zyprexa had worldwide sales of $3.09 billion in 2001, representing an increase of 31 percent. Sales in the U.S. increased 29 percent, to $2.18 billion. Zyprexa's sales continued to experience strong growth in the face of an additional competitive product in the U.S. Sales outside the U.S. increased 38 percent, to $910.5 million, benefiting, in part, from the launch of Zyprexa in Japan during the second quarter of 2001.

69. Lilly also stated that in early August 2001, generic fluoxetine had been introduced in the U.S. market. As a result, the Company stated that sales of its drug Prozac had "experienced a very steep decline" and that further declines were expected beginning in February 2002 when the number of generic sellers of fluoxetine no longer was restricted under the federal Hatch-Waxman Act of 1984. According to the Company, Prozac sales in the U.S. had historically represented a significant portion of its overall sales, "accounting for approximately 20 percent in 2000." While the Prozac decline was expected to significantly affect results of operations for the 12 months following August 2001, the Company noted that its impact on the Company's consolidated financial position or liquidity was "***not expected to be material due to***

***the growth of the company's newer products including Zyprexa***, Humalog, Gemzar, Evista, Actos, and Xigris." (emphasis added).

70. The Company added that it anticipated "low-to-mid single-digit sales growth for 2002" and that "several key products" (including Zyprexa) were "expected to contribute to this growth."

71. At this same time, Lilly also indicated that the Company's success depended "in great measure upon ***customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness*** . . . We have developed quality-assurance procedures relating to the quality and integrity of scientific information and production processes (emphasis added).

**B. Form 10-K for Fiscal Year 2002**

72. On or about March 20, 2003, Lilly filed with the SEC a Form 10-K for Fiscal Year 2001 (ending December 31, 2001). Defendants Taurel and Golden signed Lilly's Form 10-K for Fiscal Year 2002. Pursuant to the Sarbanes-Oxley Act of 2002, this Form 10-K also included certifications signed by Defendants Taurel and Golden. In that public filing, the Company stated that its reported worldwide sales for 2002 decreased by 4 percent, to $11.08 billion, due primarily to the decline in sales of Prozac in the U.S. resulting from the loss of patent protection in August 2001. The Company added, however, that "[p]artially offsetting this decline was sales growth of Zyprexa."

73. As to Zprexa specifically, Lilly stated:

> Zyprexa had worldwide sales of $3.69 billion in 2002, representing an increase of 20 percent. Sales in the U.S. increased 16 percent, to $2.53 billion. Sales outside the U.S. increased 27 percent, to $1.16 billion, benefiting, in part, from the launch of Zyprexa in Japan during the second quarter of 2001. At the end of June 2002, our European sales forces began promoting Zyprexa for use in treating manic episodes associated with bipolar disorder.

74. At this same time, Lilly stated that for the first quarter and full year of 2003, excluding unusual items, the Company expected earnings per share to be in the range of $.57 to $.59 and $2.50 to $2.60, respectively. According to the Company, its financial expectations for 2003 included, among other items, "continued, solid growth in Zyprexa sales."

75. As it had the prior year, the Company also indicated that:

> Our success depends in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, and distribution. We have implemented quality-assurance procedures relating to the quality and integrity of scientific information and production processes.

76. Lilly further stated that in addition to a system of internal accounting controls, the Company also maintained "a code of conduct (known as the *Red Book*) that applies to all employees worldwide, requiring proper overall business conduct, avoidance of conflicts of interest, compliance with laws, and confidentiality of proprietary information." Lilly added that "The *Red Book* is reviewed on a periodic basis with employees worldwide and all employees are required to report suspected violations."

**C. Form 10-K for Fiscal Year 2003**

77. On or about March 15, 2004, Lilly filed with the SEC a Form 10-K for Fiscal Year 2003 (ending December 31, 2003). Defendants Taurel and Golden signed Lilly's Form 10-K for Fiscal Year 2003. Pursuant to the Sarbanes-Oxley Act of 2002, this Form 10-K also included certifications signed by Defendants Taurel and Golden. In that public filing, Lilly stated that its worldwide sales for 2003 increased 14 percent, to $12.58 billion, due, in part, "to the strong performance of Zyprexa, a treatment for schizophrenia, acute bipolar mania, and bipolar maintenance." As for Zyprexa sales, Lilly indicated that the drug had worldwide sales of

$4.28 billion in 2003, an increase of 16 percent. Zyprexa sales in the U.S. increased by 4 percent, to $2.64 billion.

78. The Company added that despite "an increasingly competitive environment," it believed that Zyprexa "still ha[d] sales growth potential in the U.S." In addition, the Company stated that Zyprexa sales outside of the U.S. were solid during 2003; adding that "[t]he strong international sales growth of Zyprexa was primarily driven by increased unit volume attributable to the bipolar mania indication and the ongoing conversion from typical to atypical antipsychotics and, to a lesser extent, the impact of exchange rates." According to the Company, Zyprexa recorded strong growth in several key markets, "including several major European Union countries and in Japan." The Company further expected "continued strong overseas growth of the product in 2004."

79. As for its expectations going forward, the Company stated that for the first quarter and full year of 2004, it expected earnings per share to be in the range of $.65 to $.67 and $2.80 to $2.85, respectively. According to the Company, this earnings guidance reflected, among other things, "ongoing domestic competitive pressures on Zyprexa," as well as "the projected benefits for Zyprexa associated with the recently approved bipolar maintenance indication."

80. This public filing also referenced Lilly's adoption of "a code of ethics that complie[d] with the applicable SEC and New York Stock Exchange requirements." The Company noted that this code was set froth in, *inter alia*, "*The Red Book*, a comprehensive code of ethical and legal business conduct applicable to all employees worldwide and to our Board of Directors."

81. The Company again reiterated that its success was dependant "in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness;" and further that Lilly had "implemented quality-assurance procedures relating to the quality and integrity of scientific information and production processes." Lilly also stated that it was "continu[ing] to review and enhance policies and procedures designed to assure that our marketing and promotional practices and physician communications comply with promotional laws and regulations."

**D. Form 10-K for Fiscal Year 2004**

82. On or about March 8, 2005, Lilly filed with the SEC a Form 10-K for Fiscal Year 2004 (ending December 31, 2004). Defendants Taurel and Golden signed Lilly's Form 10-K for Fiscal Year 2004. Pursuant to the Sarbanes-Oxley Act of 2002, this Form 10-K also included certifications signed by Defendants Taurel and Golden. In that public filing, Lilly stated that its worldwide sales for 2004 increased 10 percent, to $13.86 billion, "due primarily to the increased global sales of Strattera, Gemzar, Forteo, ***Zyprexa***, Evista, Humatrope, and Cialis, and sales related to the launches of Alimta and Cymbalta." (emphasis added). As for Zyprexa sales specifically, Lilly stated as follows:

> Zyprexa, our top-selling product, is a treatment for schizophrenia, bipolar mania, and bipolar maintenance. ***Zyprexa sales in the U.S. decreased 8 percent in 2004 due to a decline in underlying demand from continued competitive pressures. Zyprexa sales outside the U.S. increased 22 percent, driven by volume growth in a number of major markets outside the U.S.*** International Zyprexa sales growth also benefited from the impact of foreign exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 13 percent in 2004. ***While we expect Zyprexa sales in the U.S. to decline in 2005, we believe the erosion will start to slow sometime in 2005.*** . . .

83. On the issue of "quality assurance," the Company once again stated that its "success depends in great measure upon customer confidence in the quality of our products and

in the integrity of the data that support their safety and effectiveness." Lilly again added that it had "implemented quality-assurance procedures relating to the quality and integrity of scientific information and production processes."

84. At this same time, the Company again stated that it had "adopted a code of ethics that complies with the applicable SEC and New York Stock Exchange requirements." As noted by Lilly, that code was set forth in, *inter alia*, "*The Red Book*, a comprehensive code of ethical and legal business conduct applicable to all employees worldwide and to our Board of Directors."

85. Lilly once again maintained that it had "implemented" (and that it "continue[d] to review and enhance") what it termed "a broadly based compliance program that includes comprehensive compliance-related activities ***designed to ensure that our marketing and promotional practices, physician communications, and remuneration of health care professionals comply with promotional laws and regulations***." (emphasis added).

**E. Form 10-K for Fiscal Year 2005**

86. On or about March 1, 2006, Lilly filed with the SEC a Form 10-K for Fiscal Year 2005 (ending December 31, 2005). Defendants Taurel and Golden signed Lilly's Form 10-K for Fiscal Year 2005. Pursuant to the Sarbanes-Oxley Act of 2002, this Form 10-K also included certifications signed by Defendants Taurel and Golden. In that public filing, Lilly stated, *inter alia,* that "Zyprexa, our largest-selling product, contributes a significant proportion of our total sales and income, and we believe Zyprexa will continue to be a major contributor to our sales and earnings for several years."

87. The Company added that its worldwide sales for 2005 had increased 6 percent, to $14.65 billion." While the Company noted that sales growth in 2005 was affected, in part, by

decreased U.S. demand for Zyprexa, ***"[s]ales outside the U.S. increased 11 percent, to $6.85 billion, driven by growth of Zyprexa***, Alimta, and Gemzar." (emphasis added). More specifically, the Company noted that while Zyprexa sales in the U.S. decreased 16 percent in 2005, "resulting from a decline in underlying demand ***due to continuing competitive pressures***," sales outside of the U.S. in 2005 had increased by 9 percent, "***driven by volume growth in a number of major markets and the favorable impact of exchange rates***." (emphasis added).

88. The Company also stated that in September 2005, the National Institute of Mental Health had released the results of its Clinical Antipsychotic Trial of Intervention Effectiveness (CATIE) study, which showed that: (a) "Zyprexa was statistically superior on time to discontinuation in patients with schizophrenia as compared to other medications" and (b) "[p]atients taking Zyprexa also experienced significantly fewer hospitalizations for schizophrenia than patients taking other medications." While the Company added that the study had noted that "Zyprexa patients experienced greater weight gain and increases in measures of glucose and lipid metabolism than patients using other antipsychotics," it made no reference to the significant body of scientific literature (of which it was well aware) that had linked Zyprexa use with diabetes.

89. In that filing, Lilly also stated that it had "adopted a code of ethics that complies with the applicable SEC and New York Stock Exchange requirements;" and that that code was set forth in, *inter alia*, "*The Red Book*, a comprehensive code of ethical and legal business conduct applicable to all employees worldwide and to our Board of Directors." In addition, Lilly again reiterated that::

> Our success depends in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities

planning, manufacturing, and distribution. We have implemented quality-assurance procedures relating to the quality and integrity of scientific information and production processes.

90. Defendants' statements concerning Lilly's financial performance, operations, and condition as set forth in paragraphs 86 to 89 above were each false and misleading when made because they misrepresented or omitted the following material adverse facts that the Defendants knew at the time the statements were made:

(a) That the Company was aware of the clear link between Zyprexa and diabetes; and yet failed to warn the public at large of the serious and material risks associated with Zyprexa use;

(b) That the Company had engaged in an illicit scheme to offset a drop in sales that was certain to occur (and, in fact, did occur) when reports of Zyprexa's side effects surfaced, by creating a marketing plan for Zyprexa which included, as a primary component, the evaluation and pursuit of sales opportunities for the drug based on "off-label" uses;

(c) That the growth rate in Zyprexa sales would not be sustainable once information about (a) the health risks of Zyprexa and (b) Lilly's illegal marketing plan were disclosed publicly;

(d) That, by concealing information about the health risks of Zyprexa, the Company had, in fact, disregarded data that undermined the "safety and effectiveness" of the drug;

(e) That the Company's "quality-assurance procedures relating to the quality and integrity of scientific information and production" as it pertained to Zyprexa were woefully inadequate;

(f) That, by engaging in an illicit "off-label" marketing" program as to Zyprexa, the Company had not "enhance[d]" its policies and procedures designed to assure that its marketing and promotional practices and physician communications "compl[ied] with promotional laws and regulations;"

(f) That the Company's failure to warn the public of the serious health risks associated with Zyprexa use and its illicit "off-label" marketing program were a direct violation of its own code of conduct as set forth in "The Red Book;" and

(g) That the Company's illicit scheme *vis-à-vis* (a) concealing the side effects of Zyprexa and (b) engaging in a massive illegal off-label marking campaign potentially subjected Lilly to substantial regulatory fines, penalties and other legal action, thereby compromising the Company's overall financial condition and prospects. In this regard,

(i) recent press reports have indicated that Connecticut Attorney General Richard Blumenthal, in concert with counterparts in other states, has expanded an investigation into Zyprexa's marketing practices and in an interview referred to a "potentially huge claim" alleging that the Company promoted the drug to Medicaid and non-Medicaid patients for unapproved uses. Similar investigations also are ongoing in other states.

(ii) Moreover, in response to the reports of the off-labeling marketing of Zyprexa, Congresswoman Rosa L. DeLauro (D-Conn.) has urged the FDA to launch an investigation. Congresswoman DeLauro is the chair of the House Appropriations Subcommittee on Agriculture,

Rural Development, Food and Drug Administration, and Related Agencies, which has jurisdiction and oversight responsibilities of the FDA and its budget. In a statement, Congresswomen DeLauro stated: "Based on the documents provided to *The New York Times*, Eli Lilly's actions involving Zyprexa are very worrisome. In addition to illegally promoting the off-label use of the drug, Eli Lilly's internal documents show that the company also deliberately withheld important safety information about Zyprexa, which has been linked to diabetes, from doctors. Eli Lilly also encouraged primary care physicians to treat schizophrenia and bipolar disorder even if the doctors did not consider themselves qualified to do so. ***This appears to be another clear example of how drug companies are putting profits before drug safety.***" (emphasis added).

## VIII. THE TRUTH ABOUT LILLY'S FRADULENT SCHEME IS REVEALED

91. As set forth above, between December 17 and 21, 2006, THE NEW YORK TIMES published a series of articles regarding the Company and Zyprexa. Based upon secret internal Company documents, those articles concluded that the Company had engaged in a decade-long effort to conceal the health risks of Zyprexa, and had illegally promoted Zyprexa for off-label uses. *See, supra*, at ¶¶ 43-46, 61-64.

92. The publication of these articles in THE NEW YORK TIMES had a negative impact on the Company's stock price. *Id.* at ¶65. On Friday December 15, 2006, Lilly's stock closed at $54.52 per share. After publication of THE NEW YORK TIMES articles regarding Zyprexa on Sunday December 17, 2006 and Monday December 18, 2006, the Company's stock price

dropped from $54.52 per share (its closing price on December 15, 2006) to $54.05 per share on Monday December 18. The stock price continued to decline, and by December 22, 2006, reached a low of $51.13 per share. Thus, in the immediate aftermath of these various news reports, Lilly's stock dropped $3.49 or 6.4 percent (representing a loss in market capitalization of approximately $3.9 billion).

93. The above-referenced decline in Lilly's market capitalization was in addition to the over $30 billion loss of market capitalization that occurred between May 7, 2004 and October 25, 2004, a loss that was the direct result of defendants' misrepresentations and omissions as detailed herein. *Id.* at ¶¶ 2-3.

## IX. INAPPLICABILITY OF SAFE HARBOR

94. As alleged herein, the Defendants acted with scienter in that they knew, at the time that they issued them, that the public documents and statements issued or disseminated in the name of Lilly were materially false and misleading or omitted material facts; knew that such statements or documents would be issued or disseminated to the investing public; knew that persons were likely to reasonably rely on those misrepresentations and omissions; and knowingly and substantially participated or were involved in the issuance or dissemination of such statements or documents as primary violations of the federal securities law. As set forth elsewhere herein, the Defendants, by virtue of their (a) receipt of information reflecting the true facts regarding Lilly, (b) control over, and/or receipt of Lilly'sallegedly materially misleading misstatements, and (c) access to confidential proprietary information concerning Lilly were informed of, participated in and knew of the fraudulent scheme alleged herein. With respect to non-forward-looking statements and/or omissions, Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public.

95. Defendants' false and misleading statements and omissions do not constitute forward-looking statements protected by any statutory safe harbor. The statements alleged to be false and misleading herein all relate to facts and conditions existing at the time the statements were made. No statutory safe harbor applies to any of the Defendants' material false or misleading statements.

96. Alternatively, to the extent that any statutory safe harbor is intended to apply to any forward-looking statement pled herein, the Defendants are liable for the false forward-looking statement pled because, at the time each forward-looking statement was made, the speaker knew or had actual knowledge that the forward-looking statement was materially false or misleading, and the forward-looking statement was authorized and/or approved by a director and/or executive officer of Lilly who knew that the forward-looking statement was false or misleading. None of the historic or present tense statements made by the Defendants was an assumption underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such an assumption underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by the Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

## X. SCIENTER ALLEGATIONS

97. As alleged herein, the Defendants acted with scienter in that, *inter alia*, the Defendants knew or acted with recklessness with respect to the fact that the public documents and statements issued or disseminated in the name of Lilly were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth

elsewhere herein, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Lilly, their control over and/or receipt and/or modification of the allegedly materially misleading misstatements and omissions described herein, which made them privy to confidential proprietary information concerning Lilly, directly and substantially participated in the fraudulent scheme alleged herein.

98. Moreover, the ongoing fraudulent scheme described in this Complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge of individuals at the highest levels of the Company, including the Individual Defendants.

99. Furthermore, pattern evidence (*i.e.*, that a party or parties participated in a pattern of fraudulent conduct over a period of time) is directly probative of the Defendants' scienter. In this regard, in December 2005, Lilly agreed to pay $36 million to settle charges that it had promoted its drug Evista for unauthorized uses. The Company also pleaded guilty to one count of violating the Food, Drug, and Cosmetic Act. The settlement called for Lilly to pay $24 million to resolve the civil action, to pay a $6 million criminal fine, and to make a $6 million forfeiture to the government. Evista is approved by the FDA for the prevention and treatment of osteoporosis in post-menopausal women. The Justice Department contended that after Evista experienced disappointing sales, Lilly tried to broaden the market for the drug by promoting it for unapproved uses.

## XI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

100. The market for Lilly's securities was open, well-developed and efficient at all relevant times for the following reasons (among others):

(a) The Company's shares met the requirements for listing, and were listed and actively traded on the NYSE;

(b) As a regulated issuer, Lilly filed periodic public reports with the SEC;

(c) Lilly regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(d) The market reacted to public information disseminated by Lilly;

(e) Lilly was followed by numerous material securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

(f) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Lilly securities; and

(g) Without knowledge of the misrepresented or omitted material facts, Plaintiffs and the other members of the Class purchased or otherwise acquired Lilly securities between the time Defendants made the material misrepresentations and omissions and the time the fraudulent scheme was being disclosed, during which time the price of Lilly securities was inflated by Defendants' misrepresentations and omissions.

101. As a result of the foregoing, the market for Lilly's securities promptly digested current information regarding Lilly from all publicly available sources and reflected such information in Lilly's securities prices. Under these circumstances, all purchasers and acquirers of Lilly's securities during the Class Period suffered similar injury through their purchase or

acquisition of Lilly's securities at artificially inflated prices and a presumption of reliance applies.

## XII. LOSS CAUSATION

102. Throughout the Class Period, the prices of Lilly's securities were artificially inflated as a direct result of Defendants' fraudulent misrepresentations regarding the Company's financial condition and operations. .

103. The Company's financial condition and operations, including Lilly's fraudulent practices *vis-à-vis* its (a) failure to warn the public of the serious health risks associated with Zyprexa use and (b) illegal "off label" marketing program were material information to Plaintiffs and the other members of the Class. Had the truth been disclosed to the market at or before the end of the Class Period, Plaintiffs and the other Class members would not have purchased Lilly stock at all, or would have done so only at substantially lower prices than the artificially inflated prices which they actually paid.

104. Defendants' fraudulent conduct, as alleged herein, proximately caused foreseeable losses to Plaintiffs and the other members of the Class. As noted above (*see, supra*, at ¶ 2), sales of Zyprexa increased from $3.69 billion to $4.42 billion between 2002 and 2004; and the Company's stock price climbed from $43.75 per share to $76.95 per share between July 18, 2002 and May 7, 2004. As reports began to emerge of a possible link between Zyprexa and diabetes (which reports were repeatedly and emphatically denied by the Defendants), sales of Zyprexa slowed and Lilly's stock price dropped from $76.95 per share to $50.34 per share between May 7, 2004 and October 25, 2004 (representing a loss of market capitalization of over $30 billion).

105. The articles in THE NEW YORK TIMES that were published between December 17 and 21, 2006 demonstrate that the Defendants knew of the very health risks that they denied and that they also purposefully marketed Zyprexa for illegal, off-label uses. Thus, the above-

referenced $30+ billion dollar decline in Lilly's market capitalization was the direct and proximate result of the Defendants' fraud, even though investors had no way of knowing of the Defendants' malfeasance until the publication of those articles.

106. In addition, in the immediate aftermath of the publication of THE NEW YORK TIMES articles between December 17 and 21, 2006, the Company's share price declined by an additional $3.49 per share, or 6.4 percent (*see, supra*, at ¶ 65), representing a further market loss of approximately $3.9 billion.

107. The decline in the Company's securities price following the revelations of the Lilly's fraudulent practices, and the resulting losses suffered by Plaintiffs and the other members of the Class, are directly attributable to the market's reaction to the disclosure of information that had previously been misrepresented or concealed by Defendants, and to the market's adjustment of the Company's securities price to reflect the newly emerging truth about the Company's financial condition. When the truth about the Company was revealed, the inflation that had been caused by Defendants' misrepresentations and omissions was swiftly eliminated from the price of the Company's securities, causing significant losses to Plaintiffs and the other Class members.

## XIII. CAUSES OF ACTION

### COUNT I
### Violation Of Section 10(b) of The Exchange Act And Rule 10b-5 Promulgated Thereunder (Against all of the Defendants)

108. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

109. This Count is asserted by Plaintiffs on behalf of itself and the Class against all the Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

110. During the Class Period, the Defendants, who owed a fiduciary duty to Plaintiffs and the class, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (b) artificially inflate and maintain the market price of Lilly's securities; and (c) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Lilly's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Defendants, and each of them, took the actions set forth herein.

111. The Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading by use of means or instrumentalities of interstate commerce; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers and acquirers of the Company's securities in an effort to maintain artificially high market prices for Lilly's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5.

112. As a result of their making and/or their substantial participation in the creation of affirmative statements and reports to the investing public, the Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, *et seq.*) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete and accurate information. The Defendants' material misrepresentations and omissions as set forth herein violated that duty.

113. The Defendants engaged in the fraudulent activity described above knowingly and intentionally or in such a reckless manner as to constitute willful deceit and fraud upon Plaintiffs and the Class. The Defendants knowingly caused their reports and statements to contain misstatements and omissions of material fact as alleged herein.

114. As a result of the Defendants' fraudulent activity, the market price of Lilly was artificially inflated during the Class Period.

115. In ignorance of the true financial condition of Lilly, Plaintiffs and other members of the Class, relying on the integrity of the market and/or on the statements and reports of Lilly containing the misleading information, purchased or otherwise acquired Lilly securities at artificially inflated prices during the Class Period.

116. Lilly knew of the very health risks regarding Zyprexa, and Lilly further knowingly marketed Zyprexa for illegal, off-label uses. Accordingly, the decline in the Company's market capitalization that occurred between May 7, 2004 and October 25, 2004 (*see, supra*, at ¶¶ 2-3) was directly attributable to Defendants' fraudulent conduct as alleged herein. Moreover, the market price of Lilly's securities also declined precipitously as a direct and foreseeable result of the first public disclosure (in December 2006) of the scheme, plan, and course of business which operated as a fraud and deceit upon the purchasers and acquirers of the Company's securities. *Id.* at ¶¶ 4, 45-46, 61-65, 102-107.

117. Plaintiffs' (and the Class') losses were proximately caused by the Defendants' active and primary participation in Lilly's scheme to defraud the investing public by, among other things, (a) concealing information about the side effects of Zyprexa and (b) engaging in a massive illegal off-label marking campaign to increase the Company's profits. Plaintiffs (and the members of the Class) purchased Lilly securities in reliance on the integrity of the market

price of those securities, and Defendants manipulated the price of Lilly securities through their misconduct as described herein. Furthermore, Defendants' misconduct proximately caused Plaintiffs' (and the Class') losses. Plaintiffs' (and the Class') losses were a direct and foreseeable consequence of Defendants' failure to disclose and their concealment of, *inter alia*, the true state of the business operations and financial condition of Lilly.

118. Throughout the Class Period, Defendants were aware of material non-public information concerning Lilly's fraudulent conduct (including the false and misleading statements identified herein). Throughout the Class Period, Defendants willfully and knowingly concealed this adverse information regarding the side effects of Zyprexa and Lilly's massive illegal off-label marking campaign, and Plaintiffs' (and the Class') losses were the foreseeable consequence of Defendants' concealment of this information.

119. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their respective purchases and sales of Lilly securities during the Class Period.

**COUNT II**
**Violation of Section 20(a) of the Exchange Act**
**(Against the Individual Defendants)**

120. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

121. As alleged herein, the Individual Defendants acted as controlling persons of Lilly within the meaning of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). By virtue of their executive positions, and/or Board membership, as alleged above, these individuals had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which

Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's internal reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

122. In particular, the Individual Defendants had direct involvement in the day-to-day operations of the Company and therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

123. As set forth above, the Individual Defendants and Lilly committed a primary violation of Section 10(b) and Rule 10b-5 of the Exchange Act by the acts and omissions alleged in this Complaint. By virtue of their positions as controlling persons of Lilly, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchase or acquisition of Lilly securities during the Class Period.

## XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action;

(b) Awarding compensatory damages in favor of Plaintiffs and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

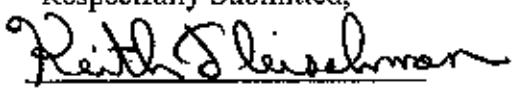
(d) Awarding such other and further relief as the Court may deem just and proper.

## XV. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury on all claims set forth herein.

Dated: March 28, 2007

Respectfully Submitted,



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*Counsel for Plaintiff and Proposed Lead Counsel for the Class*

**CERTIFICATION OF NAMED PLAINTIFF**
**PURSUANT TO FEDERAL SECURITIES LAWS**

I, Robert A. Smith (Plaintiff) declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed the Complaint and retains Schiffrin Barroway Topaz & Kessler, LLP and such co-counsel it deems appropriate to associate with to pursue such action on a contingent fee basis.

2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in any private action.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. Plaintiff's transactions in the Eli Lilly & Company (NYSE: LLY ) that are the subject of this action during the Class Period are as follows:

| No. of Shares | Buy/Sell | Date | Price Per Share |
|---|---|---|---|
| 50 | BUY | 9/16/2003 | $61.86 |
| 450 | BUY | 5/12/2004 | $73.98 |
| 250 | SOLD | 2/1/2005 | $54.21 |
| 250 | SOLD | 10/18/2005 | $51.74 |

List additional transactions on a separate sheet of paper, if necessary.

5. During the three years prior to the date of this Certification, Plaintiff has sought to serve or served as a representative party for a class in the following actions filed under the federal securities laws: n/a

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24th day of March, 2007

Robert A Smith

ROBERT A. SMITH

**CERTIFICATION OF NAMED PLAINTIFF**
**PURSUANT TO FEDERAL SECURITIES LAWS**

I, Scott J. Sebastian (Plaintiff) declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed the Complaint and retains Schiffrin Barroway Topaz & Kessler, LLP and such co-counsel it deems appropriate to associate with to pursue such action on a contingent fee basis.

2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in any private action.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. Plaintiff's transactions in the Eli Lilly & Company (NYSE: LLY) that are the subject of this action during the Class Period are as follows:

| No. of Shares | Buy/Sell | Date | Price Per Share |
|---|---|---|---|
| 10 | BUY | 10/5/2005 | $53.945 |
| 5 | BUY | 10/21/2005 | $50.884 |
| 35 | BUY | 11/13/2006 | $53.91 |
| 20 | BUY | 11/22/2006 | $53.99 |

List additional transactions on a separate sheet of paper, if necessary.

5. During the three years prior to the date of this Certification, Plaintiff has sought to serve or served as a representative party for a class in the following actions filed under the federal securities laws: n/a

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27TH day of MARCH, 2007

SCOTT J. SEBASTIAN